

STERILIZATION

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Sterilization



Steam Sterilizer

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OBJECTIVES

Following training, the employee will be able to:

1. Explain the characteristics of ethylene oxide.
2. State the permissible exposure limits set by OSHA.
3. Discuss STEL and TWA.
4. Explain monitoring systems.
5. List the personal protective equipment necessary when changing EtO tanks.
6. Discuss the proper handling and storage of EtO tanks.
7. List sterilizers by type.
8. In general, name the component parts of each of the sterilizers.
9. Describe the cycle of the types of sterilizers.
10. Define implants.

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STERILIZATION

1. PRINCIPLES

a. Sterilization means the act or process of completely destroying all forms of microbial life. This is an absolute. There is no condition as almost sterile, practically sterile, or sterile to a degree. The medical center practice for sterility must be all or none. There can be no in between. Sterility must be measured by proper sterility tests and methods. Achievement of true sterilization is a function of probability, and the process is influenced by the laws of chance. Many factors that can influence the end result of sterilization are:

- (1) The number of organisms and their resistance to the sterilization agent.
 - (2) Debris left on the item to allow protection to the organisms, such as protein soil, oils, grease, blood, etc.
 - (3) Sterilizer functional efficiency. Proper function.
 - (4) Shortcuts used to increase productivity.
 - (5) The human element. Performance of people cleaning, packaging, and monitoring the sterilizers.
 - (6) Proper loading techniques.
 - (7) Handling techniques after the process.
 - (8) All parameters of each method of sterilization must be achieved.
- b. Sterilization is a complex process and there is no practical way of proving that an item is actually sterile without contaminating it. It is then necessary to verify that an item has been exposed to a processing cycle in a sterilizer. To verify the sterilizer cycle certain tests and monitoring procedures are necessary.

2. STEAM STERILIZATION

a. Moist heat in the form of saturated steam under pressure is the killing agent used in steam sterilization to destroy all forms of microbial life, including viruses and spores. Steam, the vapor into which water is converted when heated to the boiling point, is a combination of heat, energy and water. Heat energy will destroy microorganisms, but steam, or moist heat, will destroy microorganisms at a lower temperature with less exposure time. By lowering the temperature and limiting the exposure time, the integrity or life of certain medical supplies is greatly extended. The most resistant pathogenic

organism is killed in hot air after an exposure of one hour at 340 degrees F. This same organism is killed at 250 degrees F after a 12-minute exposure in saturated steam.

b. Death by moist heat is caused by coagulating the protoplasm, which is the life blood of the microorganism, thus eliminating reproduction. The coagulating of the microorganism's protoplasm can be compared to the chemical change that occurs in the white of an egg when it is poached.

c. Factors greatly affecting the steam sterilization process are: surface contact, time-temperature, and temperature-pressure.

3. SURFACE CONTACT

Effective steam sterilization is dependent on the ability of the steam to have direct contact with all surfaces, including every strand, fiber, or particle of the device or product being sterilized. There are several conditions that can inhibit sterilant contact. Inadequate air removal from the sterilizer chamber, which will prevent steam from contacting all surfaces of the product being sterilized. Steam does not mix with air, therefore, air will act as a barrier between the steam and the surface to be sterilized. Improper handling techniques before the actual sterilizing process can greatly affect sterilant contact. All items must be cleaned properly and placed in the sterilizer in such a manner to aid sterilant contact and not impede it.

4. TIME-TEMPERATURE

a. The time-temperature relationship is necessary to accomplish terminal sterilization in saturated steam. The minimum time to kill known quantities of the most resistant forms of microbial life at various temperatures have proven to be as follows:

30 minutes at 250 degrees F
4 minutes at 270 degrees F

As the temperature increases, the kill time is decreased.

b. The exposure period in a steam sterilizer is the total of heat up minutes, kill time minutes, and safety-factor minutes. The heat up minutes is the time required for the load contents to come to temperature, AFTER the chamber has reached the selected sterilizing temperature and all the air has been removed from the chamber.

5. TEMPERATURE-PRESSURE

a. Pressure does not kill microbial life, but is used in sterilization only to increase temperatures. At sea level atmospheric pressure, water freezes at 32 degrees F and boils at 212 degrees F. Higher or lower pressure will change these values. At an elevation of 5,000 feet above sea level, water will boil at approximately 190 degrees F

instead of 212 degrees F, because of the lower atmospheric pressure. Depending on pressure, water will boil anywhere from 35 degrees F to 704 degrees F. Pressure increases the saturated steam temperature so that it is possible to reach the necessary kill-temperatures to destroy the most resistant forms of microbial life.

b. There is a constant relationship between temperature and pressure for the proper steam quality. If the temperature is raised or lowered, then the pressure must be raised or lowered. It is important to note that the geographic location where the sterilization process is taking place affects the pressure required to reach the kill temperature. Pressure must be increased by .5 pounds for each 1,000 feet above sea level. This increased pressure compensates for the decreased atmospheric pressure.

6. STEAM QUALITY

a. The efficacy of the sterilization process can be affected by the quality and purity of the steam being used. Steam quality refers to the moisture content of the steam. Sterilization failure can result if the steam is either too "wet" or too "dry." Sterilization failure can also result if the steam is not pure. Steam purity refers to the degree of solid, liquid, or vapor contaminants in the steam.

b. Steam used in sterilization is known as Saturated steam. It is necessary to have saturated steam, which is 97 percent dry with a 3 percent moisture content, for effective steam sterilization. Saturated steam has a constant relationship between temperature and pressure. The temperature of saturated steam cannot be reduced or increased without reducing or increasing the pressure.

c. Saturated steam subjected to temperature increases without the corresponding pressure increase becomes superheated steam. Superheated steam is 99 percent dry steam with a 1 percent moisture content. Superheated steam is "dried out" and does not have the necessary moisture content that is so important for the steam sterilization process. If superheated steam is used for sterilization, fabrics can become scorched or burned. Using superheated steam can result in sterilization failure. Sterilizing fabrics that are too dry may cause superheating because the dry fabric will absorb excess amounts of moisture. Fabrics should be laundered and rehydrated between each sterilization process or if the item becomes outdated on the shelf. Fabrics should never be ironed. Ironing causes the fabric weave to tighten which would inhibit steam penetration. Ironing dries out the fabric which causes it to absorb excess amounts of moisture which results in superheating. Outdated linen packs should never be "sprinkled" with water and resterilized. They must be laundered and rehydrated.

d. If saturated steam is subjected to temperature decreases without the corresponding pressure decrease, it becomes wet steam. Wet steam is 91 percent dry steam with 9 percent moisture content. Wet steam may occur at peak operation periods when the excessive demand placed on the boiler may lower temperatures. Improper trapping of the steam line to the sterilizer permits a buildup of moisture in the lines immediately adjacent to the unit, or an uninsulated line allows the steam in the line to

cool, producing excessive moisture. Steam with a high moisture content can cause wet packs in the sterilization process. Water provides a direct pathway for microorganisms. Packs that are wet will not maintain sterility and must not be used.

e. Steam sterilization can be affected by impure steam, which contains solid, liquid, or vapor contaminants. The steam may be considered sterile (it does not contain microorganisms), it is far from "pure." Impure steam can cause linen spotting and instrument staining. Causes of impure steam are:

- (1) Solid impurities - rust, pipe scale deposits, sludge, particles from gasket materials, etc.
- (2) Liquid impurities - boiler feed water additives used to control the pH level and to retard scale and corrosion.
- (3) Vapor impurities - volatile amine additives used to prevent corrosion in steam lines and condensate return lines.

f. Steam impurities may result from steam reacting with additives in wrapping material. If linen is not rinsed thoroughly or if treated with chemicals not compatible with steam, impurities will result. If problems arise that appear to be caused by steam impurity, it is important to determine the source of the problem. Discussing the problem with Engineering Service, boiler maintenance workers, sterilizer manufacturer, or the laundry plant manager, may help in discovering the source of the problem. Once the problem is discovered additives may need to be changed, filters installed, etc.

7. BASIC STERILIZER FUNCTION

Two basic steam sterilization cycles are the Gravity Displacement Cycle and the Prevacuum Cycle. The steam sterilizer consists of ten basic parts:

- a. Door
- b. Jacket
- c. Chamber
- d. Steam Inlet
- e. Chamber Drain
- f. Pressure Gauge
- g. Temperature Gauge
- h. Operator Controls
- i. Mechanical Monitoring Controls
- j. Vacuum Pump (for use with the prevacuum units only)

8. GRAVITY DISPLACEMENT CYCLE

a. Steam is first injected only into the jacket until pressure at the proper range has been reached. This pressure is maintained throughout the sterilization cycle. This process heats the sterilizer chamber which prevents condensation from forming on the otherwise cool interior chamber walls which would consequently cause wetting of the load.

b. Then the cycle is initiated, the chamber and contents are full of air. The chamber drain is open. Steam is injected through the steam inlet valve, usually located near the upper back section of the sterilizer chamber. Because air is nearly twice as heavy as steam, it is pushed or displaced to the bottom of the sterilizer and out through the chamber drain line as the volume of steam is increased. Steam penetrates throughout the load slowly as it displaces the air. It is important to remember this concept of top to bottom flow of steam. If the items are not packaged correctly or the sterilizer is not loaded correctly, air may become trapped because the steam cannot push it out.

c. Steam will continue to enter the sterilizer chamber during the gravity cycle until the thermometer, located in the chamber drain line, registers the preselected temperature. The thermometer is located in the chamber drain line since it is the last area to be reached by steam and the coolest area.

d. The exposure phase is next. Once the thermometer registers the correct temperature, the timing mechanism will be activated, the steam inlet valve and the chamber drain valve will close, and the preselected exposure time will begin. If a drop in the temperature is registered, the steam injection valve will open and add steam into the chamber. Once the correct temperature is maintained, the steam inlet valve will again close.

e. Once the exposure phase is complete, the exhaust phase begins. Steam is quickly exhausted to atmospheric pressure. Sterile filtered air is mechanically injected into the chamber to aid in the cooling and drying of the load contents. At the end of this phase, the chamber door is opened slightly, leaving the cart with the sterile items inside the chamber to continue the drying process. At the end of the cycle, after the door has been ajar, the cart is moved to the cool down area where the items continue to cool.

9. PREVACUUM CYCLE

a. In this cycle, steam is first injected only into the jacket until pressure at the proper range is reached, and this pressure is then maintained throughout the sterilization cycle. This process heats the sterilizer chamber which prevents condensation from forming on the otherwise cool interior chamber walls which would consequently cause wetting of the load.

b. The conditioning phase begins with an initial purge. Steam is injected through the steam inlet valve which displaces the air to the bottom of the sterilizer and out through the opened chamber drain line. The initial purge is followed by a series of steam pulses and vacuum pulls.

(1) **Steam Pulse.** The chamber drain valve is closed and steam is injected through the steam inlet valve.

(2) **Vacuum Pull.** The steam inlet valve is closed and the air/steam is pulled from the chamber and load by the use of a powerful vacuum pump which creates a negative pressure within the sterilizer chamber and load.

c. The pulse/pull sequence consists of three steam pulses and four vacuum pulls. Packaging and loading are less likely to interfere with air removal in the prevacuum cycle because the vacuum pump pulls the air from the items to be sterile. It is still vital to follow correct loading techniques, as is done for all sterilizers utilized.

d. After the last pull, there is negative pressure within the chamber and items to be sterilized. When steam is introduced into this vacuum, it penetrates the chamber and load quickly in a very turbulent manner since it is not impeded by air. Steam will continue to enter the sterilizer chamber until the thermometer located in the chamber drain line registers the preselected temperature.

e. The timing mechanism will be activated at this point, the steam inlet valve and the chamber drain valve will close, and the exposure time will begin. If the thermometer registers a drop in temperature, the steam injection valve will open and steam will be injected into the chamber. Once the temperature is reached, the steam inlet valve will again close.

f. Upon completion of the exposure phase, the steam is mechanically removed by the vacuum pump. Sterile filtered air is then mechanically injected into the chamber to relieve the vacuum. Once the cycle is complete, the door is opened and the cart, with the dry items, is moved to the cool down area where the sterile items continue to cool.

10. FLASH STERILIZATION

a. The philosophy behind "flash" sterilization has been accepted for years. Recommendations from JCAHO, AMMI, and AORN now state that flash sterilization should only be used in an emergency. This is for items that are dropped and/or single instruments that may be called for during a case, that are not already sterile. It is not recommended, however, to flash large trays of instruments, such as loaner trays or to flash IMPLANTS.

b. If loaner trays and implants are to be used for a case, they should be received into SPD in advance of the scheduled case and properly cleaned, assembled, sterilized and

quarantined. (Implants only are to be quarantined. Remember, screws and plates in orthopedic trays are considered implants.) It is imperative that the medical center develop a protocol for handling instrument trays that are used on a loaner basis. This needs to be accomplished by the Chief, SPD.

c. If an instrument set is needed for another case scheduled for the same day, enough time must be allocated by the operating room to send their set of instruments to SPD for decontamination and sterilization. Instruments should not be cleaned in the operating room by scrub nurses, then flashed. This practice will lead to cross-contamination, and can cause grave outcomes with the patient. It is the responsibility of the Chief, SPD, and the Operating Room Manager to determine if additional sets of instruments are necessary to avoid reprocessing and sterilization of instrument sets needed for another case for the same day.

d. Flash sterilizers are basically gravity displacement sterilizers set on the "open" cycle or nonwrapped cycle. The items to be flashed should be placed within the tray to avoid overcrowding and should not be overloaded. There should be no towels in the tray. Items with lumens, such as suction tubes, will not be flashed and power equipment should never be flash sterilized, due to their complex makeup.

e. All sterilizer cycles should be monitored. Monitoring sterilization cycles will be discussed later in this chapter.

f. All sterilization cycles require accurate documentation and record keeping. This includes all flash sterilization loads. All items processed through the cycle should be listed, along with the sterilizer number, load number, date, and print out or graph from the sterilizer. The Chief, SPD, will be required to track all sterilizer loads processed in the operating room as well as within the medical center.

11. EtO (ETHYLENE OXIDE) STERILIZATION

a. EtO gas has been an effective sterilant for heat and moisture sensitive medical devices for more than a quarter century. However, because of its toxic nature, EtO must be used with caution and only by individuals properly trained in its safe use.

b. The process of alkalization inactivates the cell, causing a chemical interference which disrupts the reproductive process of the microorganisms, thus destroying them. Hence, sterilization is achieved. It is recommended that ONLY heat sensitive items be EtO sterilized, only items that ABSOLUTELY cannot be sterilized by steam. EtO sterilization is expensive and too time consuming to tie up needed medical supply items.

c. All items processed in EtO must be thoroughly cleaned and dried prior to sterilization. If water and EtO mix during the cycle, a by-product, polyglycol is

produced. This byproduct can be hemolytic, or in other words can destroy blood cells. Always assure all items have been properly dried prior to sterilization.

d. Two types of ethylene oxide sterilizers are most commonly used. They are table top or smaller chamber stand alones that utilize 100 percent EtO cartridges, and the larger units that utilize the most common EtO mixture of 88 percent freon and 12 percent EtO. A well designed ventilation system must be in place when using either method. The EtO mixture containing freon will no longer be allowed for use in any facility due to the chloroflorcarbins (CFC's), admitted into the atmosphere, so many facilities are looking to other methods to sterilize heat sensitive items. Many of these methods are still in the testing phase, and it is recommended to research these new sterilizers in depth, prior to purchasing them. More information on these sterilizers will be discussed later in this chapter.

e. Many of the existing EtO sterilizers in use consist of the following phases:

(1) Vacuum phase, which creates a partial vacuum drawn for a brief time, to remove most of the residual air from the chamber and from the packaged items in the load. Once the desired vacuum has been reached, steam is injected into the chamber and diffuses throughout the load, beginning a 20- to 30-minute conditioning period, during which the contents of the load reach a relative humidity of 50 to 75 percent and the desired temperature is reached.

(2) The ethylene oxide gas or gas mixture is admitted, and as the sterilant is injected, the chamber pressure rises to the pressure required to achieve sterilization.

(3) The sterilizer then remains in the exposure phase for the preset time. The chamber is continually maintained at the correct pressure, humidity, and temperature. Once this phase is completed, a vacuum is pulled (sometimes called the "purge" cycle), removing the gas from the chamber and exhausting it to the outside atmosphere.

(4) Once this phase is complete, or the chamber is exhausted, air is drawn into the chamber through a bacteria retentive filter and then reevacuated from the chamber, removing most of the ethylene oxide. This air wash is continued for a period of 10 to 30 minutes.

(5) At the end of this phase, the chamber is returned to atmospheric pressure. Some sterilizers continue the filtered air purge until the door is opened.

f. Many EtO sterilizers are equipped with an aeration cycle at the end of the sterilization cycle. This allows the load to completely aerate prior to opening the door or touching the items. This is the safest way to EtO sterilize. If there is not an aeration cycle at the end of the sterilize cycle, the door must be cracked for 15 minutes and all staff should remain away from the area. Once the time is completed, the load may be moved to the aerator.

g. To move a load to the aerator, the sterilizer operator should always remember to pull the load, never push it. Pull the cart to the aerator, then slide the load into it, close the door and begin the cycle immediately. All items sterilized by EtO must be aerated. Typical aeration time and temperature is 12 hours at 122 degrees F, but the manufacturer's instructions should always be consulted. Items that are not properly aerated can cause burns to the patient, physician, or staff handling the item.

h. Room aeration, or ambient aeration, is not recommended. With ambient aeration, items are placed in an isolated, well ventilated room and the gas allowed to dissipate slowly over a period of time, usually several days.

12. LOADING THE EtO STERILIZER

a. The packaged items to be sterilized should be placed on metal sterilizer carts or in wire baskets. The use of metal carts minimizes handling of sterile items and, because metal does not absorb ethylene oxide, allows safe transfer of items from the sterilizer to the aerator.

b. When the items are loaded on the cart, they should be arranged loosely to ensure the sterilant will circulate freely and reach all surfaces. The items must not touch the sterilizer chamber walls during the cycle. Loading the EtO sterilizer should be done in much the same manner as loading the steam sterilizer.

13. STERILIZATION MONITORING

a. Because such a variety of parameters must be met to achieve sterilization, monitoring the process is essential. The methods used for monitoring the sterilization process are chemical, biological, and mechanical.

b. Chemical indicators consist of paper chemically treated to change color when subjected to the sterilization process. There are internal and external chemical indicators.

c. Internal chemical indicators are placed inside packages. The internal chemical indicator alone does not guarantee sterility, but provides an indication to the user that the contents of the package were subjected to sterilizing conditions. However, if the indicator has not completely changed its color, the contents may not have been subjected to a full scale sterilizing process and, therefore, should not be considered sterile.

d. External chemical indicators are placed on the outside of packages and are commonly used as package closure, as in the case of sterilizer tape. External chemical indicators also do not alone guarantee sterility, but that the package has been exposed to a sterilizing cycle. The external indicators must be examined for proper complete color change after sterilization and again prior to distribution to eliminate the possibility of distribution of items not processed.

e. Another test performed, but only on prevacuum sterilizers, is the Bowie-Dick test (named for the scientists who invented it). These test packs can be assembled in SPD or purchased preassembled from the manufacturer. The Bowie-Dick test is performed daily according to the manufacturer's instructions to test the effectiveness of the vacuum system. It is not a sterilization test. The packs contain a chemical indicator which turns color when an effective vacuum has occurred. The packs should be placed in the sterilizer on the bottom rack over the drain in an otherwise empty chamber. This area is chosen because it is the most difficult area in the chamber to create an effective vacuum. At the end of the cycle, the indicator within the pack is examined for a uniform color change to indicate a complete vacuum within the chamber.

f. A biological indicator contains live spores and provides a further indication of an effective sterilization process. *Bacillus stearothermophilus* are the spores used in steam sterilization and *Bacillus subtilis* are used in EtO sterilization.

g. The biological indicators contain an amount of spores that far exceeds the amount of bioburden possibly left on items after the decontamination process and before sterilization. The sterilization process is designed to kill the excessive amount of spores within the biological indicator and, therefore, provide a margin of safety.

h. Biological indicators are placed in a fully loaded chamber and run with every EtO sterilization cycle. They are run in a fully loaded steam sterilization cycle once a day, with every load containing an implantable device, and after each major repair of the sterilizer. After the cycle, the indicator is incubated either in the lab or, if appropriate, in SPD. Steam biological indicators are incubated at 55 degrees C and EtO biological indicators at 37 degrees C. Both are incubated for 48 hours. At 48 hours, the indicators are examined. If they show a color change, this indicates growth of the spores and, therefore, a kill was not obtained and the sterility of the load not indicated. When the color does not change, this indicates no growth and that sterility was achieved. A "control" indicator should be processed daily for each type of sterilization (steam or gas) to assure that the spores are viable. These controls must be from the same lot number as the test biologicals.

i. In the event of a positive biological indicator, it must be determined whether it was due to sterilizer malfunction, user error, or contamination of the indicator following sterilization. If sterilizer malfunction or user error is determined, the load must be recalled, reprocessed, and resterilized. All items bearing the load number of the load containing the positive microorganisms other than *Bacillus stearothermophilus* or *Bacillus subtilis* within the indicator, contamination after sterilization and prior to incubation is assumed.

j. Mechanical monitoring is accomplished by gauges, recorders, graphs, etc., that indicate the proper sterilization parameters have been met. This may either be done manually or by automated readouts, depending on the sterilizer equipment. Both manual and automatic monitoring must be verified at the completion of each sterilization cycle.

k. Records must be kept of all sterilization monitoring done in the medical center. The contents of each load, the operator, the length, temperature, and other required parameters must be documented for each load run in both steam and EtO sterilizers. The results of the Bowie-Dick tests and the biological indicators must be documented as well.

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STERILIZERS

1. TYPES OF STERILIZERS

a. There are several types of equipment used for terminally sterilizing medical supplies and equipment. Types of sterilizers to be discussed include prevacuum steam, gravity displacement steam, ethylene oxide, dry heat, chemical, and plasma sterilizer.

b. Steam and ethylene oxide sterilizers are the two most common units used in hospitals and clinics. Those units are preferred because the sterilizers are effective in killing microorganisms and are relatively inexpensive. There are several variations of each type of unit, they vary in size and function.

c. Personnel must be trained thoroughly before they operate any sterilizing equipment. Operating a sterilizer is a demanding part of the SPD technicians job. If it is not done properly, the instruments or supplies used may cause infection to the patient.

2. STEAM STERILIZERS

a. Steam under pressure is one of the most reliable methods for sterilizing items that can withstand high temperatures and moisture. Steam is very effective in killing microorganisms. It is relatively easy to produce, inexpensive, and the process can be effectively monitored.

b. **Prevacuum Steam Sterilizers.** Component parts consist of a double walled (jacketed) chamber, a pressure door (depending on the model, the door can be manually or automatically operated), a control panel, and monitoring gauges. The unit can come in different sizes, from a large floor model to a unit capable of handling only a few supplies. The unit is connected to a steam fed system, as well as a steam condensing system that converts the steam into water following the sterilizing operation. The water is discharged into a floor drain. The body of the sterilizer can be encased in a stainless steel cabinet, however, the plumbing and the body of the sterilizer are usually contained in a dedicated room, only the door, control panel, and gauges are visible to the staff. Processing temperature for this equipment ranges from 250 degrees F to 275 degrees F. Each sterilizer cycle consists of several phases. A typical prevacuum cycle is as follows:

(1) Phase 1 – Prevacuum 1 – a vacuum is pulled to remove the air from the chamber and the interior of the packages. In this phase most of the air is removed from the chamber.

(2) Phase 2 – Exposure – the length of time and temperature of this phase is predetermined by the operation. The chamber temperature is maintained when additional steam is injected into the chamber to replace cooled steam.

(3) Phase 3 – Come down – at the end of the sterilize phase, the bottom drain opens and allows the steam to evacuate the chamber.

(4) Phase 4 – Drying – at atmospheric pressure, the drying phase is begun. The jacket temperature aids in the drying of the load. Gravity-displacement sterilizing is a much longer process than prevacuum sterilizing. When the determined time is over, an audio and visual alarm sounds. The cycle is completed. Large, dense packs will take longer to process because of the extended time for air to be removed from them.

f. Liquid loads should always be run on a gravity cycle. This cycle however, is somewhat different from the cycle described above. Liquids take longer to run. Generally a cycle is as follows:

(1) Phase 1 – Come up – the drain at the bottom of the chamber and a valve at the upper part of the chamber open and steam is injected into the chamber. As the steam concentration increases, the air in the chamber is forced out through the bottom drain. The steam will continue to be forced into the chamber until the predetermined temperature is reached.

(2) Phase 2 – Exposure – the length of time and the temperature of the phase is predetermined. The chamber temperature is maintained when additional steam is injected into the chamber to replace cooled steam.

(3) Phase 3 – Come down – at the end of the sterilize phase, the bottom drain opens in gradual increments. This is done so that the pressure can be released slowly to allow for the liquids to cool. This process can take up to 30 minutes or longer, depending on the load contents. After the cycle, the temperature must be allowed to drop to at least 200 degrees F before the chamber door can be opened. The technician must use great care when handling containers of liquids following sterilization. The contents can boil over or explode and injury may occur. Extreme care must be used when running liquid loads. All operating instructions must be strictly followed when operating a liquid cycle.

NOTE: No other items should be run with liquids. Select the temperature 250 degrees F. Exposure time is based on the amount of liquid in the container. No dry time is to be set.

h. **Table Top Steam Sterilizers.** These types of gravity-displacement sterilizers are usually found in dental offices or clinics. It is a small unit that can be placed on a counter. The unit has an electric generator that turns water into steam. The air is

forced out of the chamber and steam is injected into the chamber for a predetermined time.

3. DRY HEAT STERILIZERS

a. This method of sterilization uses air at elevated temperatures to sterilize. The principle of the operation is that hot air is circulated over items for specific periods of time. The amount of time needed to sterilize an item will depend on the temperature selected. The microorganism and the cellular debris are literally burned up during the process.

b. These sterilizers are used to sterilize instruments (which includes suture needles), glassware, some types of powders, and petroleum base gels.

c. However, sutures, most types of powders, and gels can now be purchased pre-sterilized. There are two types of dry heat sterilizers – gravity and mechanical.

d. **Gravity Dry Heat Sterilizer.** The heating element is at the bottom of the unit. As heat rises, it heats the instruments to the desired temperature. This continues until the unit times out.

e. **Mechanical Dry Heat Sterilizer.** This unit works essentially the same as the gravity unit except that it has a system that recirculates the air through the sterilizing chamber. This unit heats the load more evenly. The sterilizing process with this unit is more controlled.

4. ETHYLENE OXIDE STERILIZER

a. This type of sterilizer is used to sterilize heat and moisture sensitive items. Ethylene oxide (EtO) is a toxic substance and a cancer and reproductive hazard. Technicians must follow all work practices designed to minimize any contact with EtO.

b. **Ethylene Oxide 12/88 or 10/90 Mixture.** Component parts consist of chamber, pressure door (depending on the model, the door can be manually or automatically operated), a control panel, and monitoring gauges. The unit can come in different sizes, from a large floor model to a unit capable of handling only a few supplies. The unit is connected to a steam fed system, as well as a steam condensing system that converts steam and sterilant into a liquid that is discharged into a floor drain. The sterilizer uses a gas mixture 10 or 12 percent by weight, ethylene oxide, and a carrier gas chlorofluorocarbon 88 or hydrochlorofluorocarbon 90 percent by weight. This mixture is fed into the sterilizer from gas cylinder(s). The body of the sterilizer, plumbing, and cylinders are contained in a dedicated room under negative pressure. Only the door, control panel, and gauges are visible to the staff. The purpose of a dedicated room under negative pressure is to reduce employee exposure to EtO. Some SPDs have

installed an additional room around the door. This area is also under negative pressure. A typical EtO cycle would be as follows:

(1) Phase 1 – Vacuum/Conditioning – the bottom drain in the chamber opens and a vacuum is drawn. When the proper pressure level is reached, steam is injected into the chamber and the load is moistened. This is referred to as conditioning. Conditioning aids in the sterilization process. The conditioning process ranges from 20 to 30 minutes. During this time, humidity of the chamber must reach 50 percent to 75 percent.

2. Phase 2 – Charge – EtO is injected into the chamber until a preset chamber pressure is reached.

(3) Phase 3 – Exposure – the sterilant stays in the chamber for a preset amount of time. During this time, the pressure and humidity are monitored and adjusted automatically. At the end of the cycle, the bottom drain opens and EtO is drawn out of the chamber.

(4) Phase 4 – Air wash – air is injected into the chamber and evacuated out. This process is repeated several times. The air wash phase will vary with the brand of sterilizer. At the end of the cycle, an audio or visual indicator or both will come on. Some sterilizers will reintiate the air wash phase if the machine is not attended to in a specified time.

c. Developments in new EtO mixtures. Many Central Services or SPDs have used ethylene oxide/chlorofluorocarbon- 12 (EtO/12/88) for many years. However, it has been determined by the Environmental Protection Agency (EPA) that CFCs are harmful to the atmosphere and will no longer be available as a carrier gas for use with EtO after 1995. Alternatives to EtO/CFC include EtO/hydrochlorofluorocarbon (EtO/HCFC) and EtO/carbon Dioxide (EtO/CO₂). EtO/HCFC mixture is now being marketed. However, HCFC is also a form of fluorocarbon and is scheduled to be phased out in the year 2030 or as early as 2015. In order to utilize this mixture, there must be modifications to the EtO sterilizer. EtO/CO₂ mixture is more desirable because the carbon dioxide is not harmful to the atmospheric ozone. The initial cost of the system is considerably higher than the HCFC because a weight sensing load station must be installed for use with the gas cylinders.

5. STERILIZER/AERATOR COMBINATION

Some manufacturers offer an aerator function built into the EtO sterilizer. At the end of the sterilize phase, the unit will automatically start a pre-programmed aeration phase. The standard times for aeration are 8 to 12 hours. The benefit of this type of unit is that the operator does not have to handle supplies until after aeration.



Sterilizer/Aerator Combination

6. 100 PERCENT ETHYLENE OXIDE STERILIZER

a. This type of sterilizer is often referred to as a table top sterilizer. The unit uses 100 percent EtO dispensed from a cartridge. The unit is connected to a dedicated exhaust. A typical cycle is as follows:

- (1) Phase 1 – Conditioning – the load is moistened with steam for a predetermined time.
- (2) Phase 2 – Exposure – EtO is injected into the chamber causing pressure to increase for a predetermined period of time.
- (3) Phase 3 – Aeration – EtO is evacuated from the chamber followed by an air wash.

b. As discussed earlier in this section, instruments and supplies that are sterilized by EtO must be aerated. The 100 percent EtO sterilizer may come with the option to perform an aeration function. If not, the operator must remove the load following sterilization, the load must be transferred to a mechanical aerator.

7. MECHANICAL AERATION

a. Component parts consist of a chamber and door, control panel, and a heater/blower unit. The body of the unit is usually located into a dedicated room under negative pressure. The door and control panel are set flush against the wall separating the work area from the dedicated room. Depending on the manufacturer, the unit may come with one or more temperature selections.

b. Following EtO sterilization, all items must be aerated for a specific amount of time. As outlined in MP-2, Subchapter E, sub-part 108-76.303(b) through (d):

“(b) The Chief, SPD, will establish written minimum aeration periods for all EtO sterilized items. Specific aeration recommendations should be obtained from the device manufacturer.

(c) The following is the minimum aeration time for eliminating EtO residuals in the absence of specific recommendations by the device manufacturer: Aeration in an approved cabinet at 50 degrees Centigrade (122 degrees Fahrenheit) for 12 hours.

(d) When in doubt about aeration requirements for a particular device, the time (12 hours) shown in (d) of this section may be followed. However, some materials may require even longer periods of aeration so the device manufacturer should be consulted for specific recommendations. Ambient or room temperature aeration is not authorized.”

c. A typical aeration cycle is as follows: Once the temperature and time are set, warm air is circulated into the chamber for the predetermined time. During the cycle, air in the chamber is continuously evacuated out and into a dedicated exhaust vent. Additional air is pumped into the chamber. This cycle continues throughout the aeration period. The supplies and instrumentation aerating must stay in the aerator the full cycle time. They must **NEVER** be removed before the cycle is complete.

8. NEW TECHNICAL DEVELOPMENTS IN STERILIZATION EQUIPMENT

a. In the past few years two new types of sterilizing equipment have come on the market. These units are chemical sterilizers (peracetic acid) and plasma sterilizers.

(2) **Chemical Sterilizer.** Component parts of the system include the processor unit with a built in control panel, a recording/printing device, and various sized inserts and instrument trays. This system employs peracetic acid and sterile water to clean and sterilize heat sensitive and/or immersible items. This unit can only sterilize one scope at



EtO Aerator

a time or a small instrument tray. The instrument containers cannot be sealed so the instrument set cannot be stored for future use. Therefore, instruments sterilized by this method must be used immediately after sterilization. The sterilizer operates at 50 degrees C to 55.5 degrees C and achieves sterilization in 30 minutes or less (20 minute minimum). The system can be used to process flexible and rigid scopes, microsurgery instruments, and general hard goods.

(2) **Plasma Sterilizer.** Sizes of plasma sterilization chambers vary from 2.5 to 5.0 cubic feet. The plasma sterilization process involves microwaves and a chemical compound.

b. In general terms the process is as follows: The chemical compound is turned into a vapor. The vapor passes through an electromagnetic field. Electrons are stripped from some of the atoms, accelerating the charged particles. This reaction creates a

variety of other species (particles) that kill microorganisms, including bacteria spores, by disrupting their cell membranes. The entire process is achieved in about one hour. There is no residual from the chemical so aeration is not required. The system is limited, as it is not designed to sterilize cellulose based items such as linen and paper. Examples of items that can be processed in a plasma sterilizer are rigid and flexible scopes, surgical and microsurgical instruments, surgical power equipment, glassware, etc.

ETHYLENE OXIDE (EtO)

1. HEALTH HAZARDS OF EtO

a. Items that are sensitive to extremes in temperature, pressure, or moisture may require gas sterilization utilizing EtO rather than steam sterilization. EtO is a colorless gas with an ether-like odor. Coming into contact with EtO has caused cancer in laboratory animals and has been associated with higher incidences of cancer in humans. In addition, adverse reproductive effects, chromosome damage, and neurotoxicity may also occur from EtO exposure.

b. In its liquid form, EtO exposure can cause eye irritation, lung injury, headaches, nausea, vomiting, diarrhea, shortness of breath, and cyanosis (blue or purple coloring of the skin).

2. PERSONNEL MONITORING

a. Due to the health hazards associated with exposure to EtO, the Occupational Safety and Health Administration (OSHA) requires periodic monitoring of employees who work around EtO. permissible exposure limits have been set by OSHA and are found in 29 CFR Section 1910.1047. There are two levels to be concerned about. The Short Term Excursion Limit, or STEL, requires that no employee will be exposed to an airborne concentration of EtO in excess of 5 parts of EtO per million parts of air (5 ppm), as averaged over a 15-minute period. STEL monitoring is normally taken during those times when the possibility of exposure is high, such as during tank changes and maintenance on the EtO sterilizers. An 8-hour Time Weighted Average (TWA) has also been set to ensure no employee has been exposed to airborne concentrations in excess of 1 part per million (1 ppm) during an 8-hour period.

b. Representative samples of both the 15-minute short-term exposures and the 8-hour time weighted average of EtO concentration is at or exceeds the action level of .5 ppm, but at or below the TWA of 1 ppm, monitoring for each such employee must be repeated at least every 6 months. If the initial monitoring reveals employee exposure above the 8-hour TWA of 1 ppm, the exposure problem must be remedied and the exposure levels reduced below the 8-hour TWA. Monitoring of these employees must be repeated at least every 3 months. If the 15-minute STEL is above 5 ppm, the exposure problem must also be remedied and monitoring for such employees will be repeated every 3 months. If it can be demonstrated by two consecutive measurements taken at least 7 days apart that employee exposures are below the action level of .5 ppm TWA, the frequency of monitoring for these employees can be discontinued.

c. Additional monitoring is required whenever there has been a change in the production, process, control equipment, personnel, or work practices that may result in new or additional exposures. After receiving the results of monitoring, the SPD Chief must notify the employee, in writing within 15 working days, of the results. This can be done either individually or by posting the results in an appropriate location accessible to the employees.

3. MEDICAL SURVEILLANCE

A medical surveillance program must be in place and available to all employees who are or may be exposed to EtO for at least 30 days a year. The medical surveillance will include medical examination and consultations. The medical exam will be made available to the employee: prior to assignment in SPD, at least annually, at the termination of employment in SPD, as medically appropriate for any exposure at the employee's request, and as soon as possible after potential exposure to EtO.

4. AREA MONITORING

Although not required by OSHA, many VA hospitals have installed systems to detect concentrations of EtO in the air. This is most often accomplished periodically by utilizing personnel monitoring badges. If an area monitoring system is used, the best method of EtO detection is by gas chromatography that is EtO-specific. Many area monitoring systems are available which are not EtO-specific, but will alarm merely with the presence of hydrocarbons which can be found in many cleaning solvents and alcohol. In order to prevent many false alarms in SPD and guarantee the proper response by employees in emergent situations, an EtO-specific monitoring system is necessary. The purpose of these systems is to detect high EtO levels in the work area before employees are exposed to them. Therefore, the alarm levels should be set at or below the exposure levels set by OSHA. Most systems have both a low and a high alarm. The low alarm in the work areas should be set at the action level of .5 ppm so the SPD Chief knows that action should be taken to determine the cause. The high alarm in these areas should be set at the TWA of 1 ppm. In the tank room and equipment maintenance access areas, the STEL is 5 ppm, so the alarm should be set only at this level to notify anyone working there to evacuate immediately. Of course, placement of the sensing ports for the monitoring system is important. It is recommended that a monitoring point be located in any area, directly in front of the EtO sterilizer, at the work stations in the preparation room, and directly in front of the sterilizer in the Decontamination room, if there is access to the EtO sterilizer from there.

5. EtO TANK CHANGING

As mentioned earlier, changing the tanks on the EtO sterilizer represents a high risk of exposure to EtO. Therefore, increased precautions must be taken to prevent

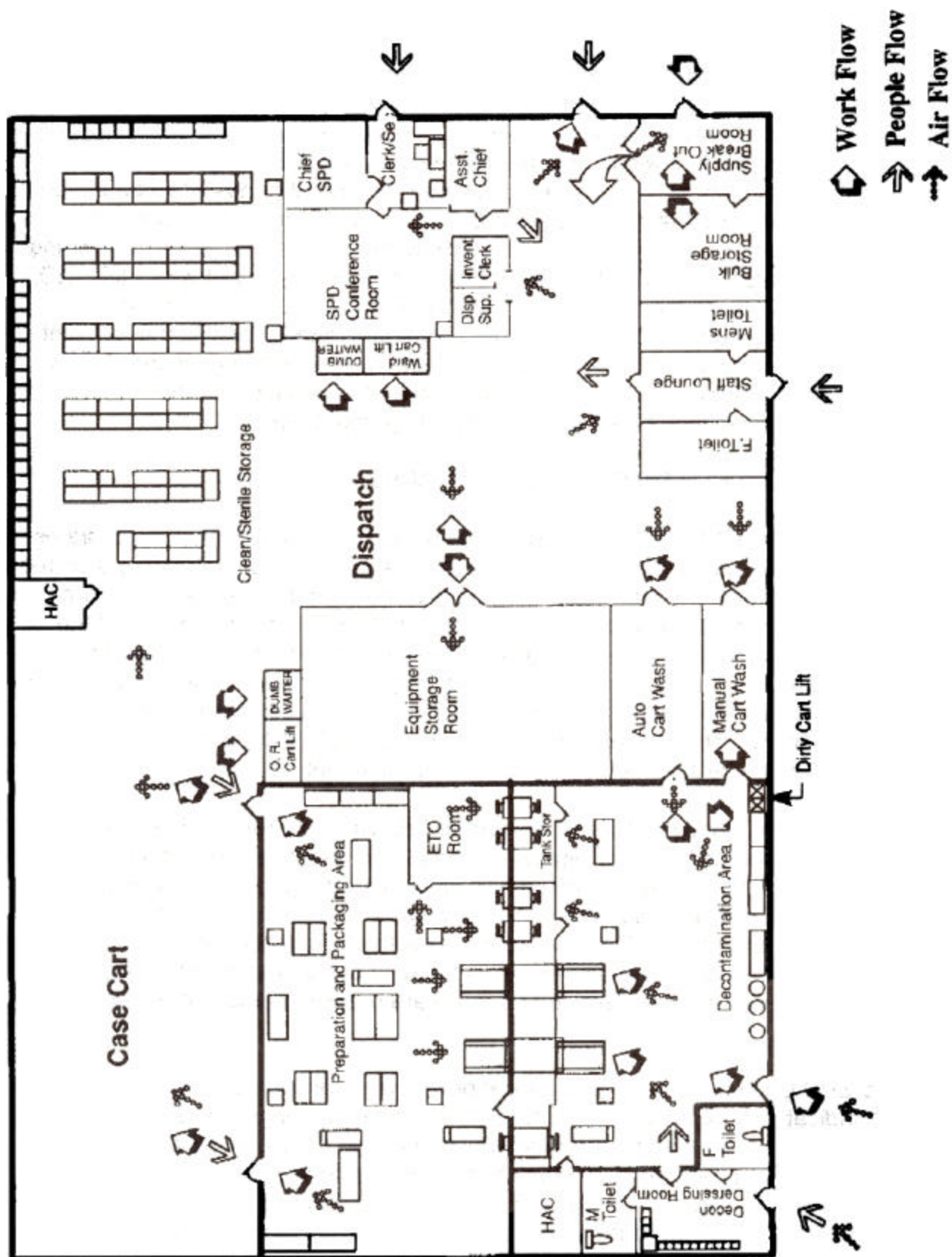
employee exposure to both the vapor and liquid forms of EtO. Personal protective clothing should be supplied and worn when changing EtO tanks, whether they are 100 EtO cartridges or 12/88 or 10/90 EtO tanks. Personal protective clothing worn should include the following: impermeable coveralls or similar full-body work clothing, gloves, head coverings. A full-face piece respirator that has been approved as being acceptable for protection against EtO should also be worn to prevent the inhalation of EtO vapors. Non sparking tools should be used when opening or closing metal containers of EtO. If impermeable clothing or skin becomes wet with liquid EtO, an SPD technician should immediately remove the clothing and EtO while under a shower. Remember, liquid EtO is easily ignited, and care should be taken to prevent any sparks or exposure to heat, flames, or other items which might cause the EtO to ignite. Fire extinguishers and showers should be readily available, and each SPD technician should know where they are and how to operate them.

6. SAFE HANDLING AND STORAGE OF EtO TANKS

a. **100 percent EtO Cartridges.** If each cartridge contents has 50 or more grams of EtO, only one day's supply of cartridges, up to a maximum of 12 cartridges, is stored in the immediate area of the sterilizers. If more than 48 cartridges are stored in the inventory are, then the storage area must conform with the recommendation of the National Fire Protection Association (NFPA). Empty containers are placed along with regular nonincinerated waste. Containers containing EtO will be returned or disposed of in accordance with the manufacturer's instructions. If such containers are not returned to the manufacturer, disposal of the containers will be done in compliance with EtO health and safety requirements and applicable local regulations.

b. **EtO Gas mixture Cylinders.** Cylinders of EtO gas mixtures, such as 88/12 or 90/10, are stored in a temperature regulated designated area that meets building codes and OSHA regulations. Tanks are stored and used in an upright position and are securely fastened in place by suitable straps or chains. Cylinders of EtO gas mixture are transported to and from SPD on cylinder carts with chains securing them during transit. All EtO cylinders are stored in an area away from the flow of traffic. Cylinders which have been used and removed from service are handled in the same manner as full cylinders.

c. The SPD Chief should develop a local policy, with concurrence by the Industrial Hygienist, indicating what steps should be taken in the event of an EtO emergency, and each SPD employee required to attend annual training on EtO, which will include: EtO sterilizer and aerator operation and maintenance, work practice/precautions for safe use of EtO, safe handling and storage of EtO tanks, physical and health hazards, accidental spill/leak plan, emergency first aid procedures, personal protective equipment, and professional EtO monitoring methods.



IMPLANTS

1. **IMPLANTABLE DEVICES. IMPLANTS** are devices that will be surgically implanted and totally contained in the body. Examples of these devices are orthopedic hardware items such as pins, screws, nails, rods, and total joint system replacement hardware; heart valves; cranial shunt and reservoirs; breast and penile prostheses; and micromesh. Implantable devices **will not** be processed by means of flash sterilization. **Every** steam and ethylene oxide gas sterilization load containing implantable devices **will** be monitored with the appropriate biological indicator. After sterilization, these devices will be held in **quarantine** by SPD, and will not be used until the spore test is found to be **negative** (after 48 hours). If an emergency situation should present itself, SPD **will** process the implant as usual and, if an **early release** is necessary, the Chief, SPD, is required to obtain a written approval from the Chief of Staff before releasing the implant from quarantine.

2. **Flash sterilization** is for emergency situations only. Adequate scheduling and planning should be utilized to have the necessary supplies on hand so that proper sterilization procedures are followed, in order not to compromise patient care.

3. **Reprocessing** implants may be necessary at times. It is important to follow the **manufacturer's guidelines** in order not to compromise or alter the implant's intended use. Some manufacturers require special gloves in handling implants and septic cleaning procedures. It is the responsibility of SPD to ensure that reprocessing does not alter the composition of the implant or alter the implant's intended use. The manufacturer will also provide information on how many times the implant can be reprocessed or if it is even possible to reprocess the implant. **Written documentation** from the manufacturer about **reprocessing guidelines** should be available and followed by **all SPD employees**. SPD **must have** a Standard Operating Procedure in order to track the number of times an implant has been used and reprocessed.

4. The **Safe Medical Device Act** became effective on August 29, 1993. The Food and Drug Administration (FDA) mandated that certain medical devices be tracked so that the devices can be located, whether in use or in stock, to notify the users or recipients of serious risk to their health. Implants fall under the medical devices that must be tracked. SPD employees should be familiar with the tracking program their medical center has developed in order to comply with the Safe Medical Device Act.

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STERILIZATION TERMS

Aeration
Aerator
Ambient Aeration
Autoclave
Chromatograph
Dry Heat Sterilizer
Ethylene Oxide (EtO)
EtO Sterilizer
Exposure Time
Guideline
Heat Resistant
Heat Sensitive
OSHA
Peracetic Acid
Plasma Sterilizer
PPM
Prevacuum
Saturated Steam
Steam Sterilizer
STEL
Sterilization
Superheated Steam
TWA
29 CFR 1910.1047

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QUESTIONS - STERILIZATION

1. Steam _____ is one of the most reliable methods for sterilizing items that can withstand high _____ and _____.
2. A jacketed sterilizer is one that is _____ walled.
3. The phases of a cycle for a prevacuum sterilizer includes _____, _____, _____, _____, and _____.
4. _____ should never be run in prevacuum cycle of a steam sterilizer.
5. Dry heat sterilizer cycles use air at _____ to perform sterilization.
6. Generally, the phases of the cycle for 100 percent EtO sterilizer are _____, _____, and _____.
7. Standard aeration times, as outlined in MP-2 Subchapter E, subpart 108-76.303(c), are: 50 Centigrade (122 degrees F) for _____ hours and 60C (140 degrees F for _____ hours.
8. Developments in new EtO mixtures include EtO _____ and EtO _____.

TRUE/FALSE

9. Plasma sterilization cycle leaves residual chemical on instruments, the load must then be aerated before the items can be used.
10. Liquid loads can only be sterilized in a gravity-displacement steam sterilizer with no dry time setting.
11. Dry heat sterilizers are capable of sterilizing some types of powders and ointments.
12. 100 percent ethylene oxide is harmful to the ozone layer of the earth's atmosphere and will be banned from use by the end of 1995.
13. Ambient or room temperature aeration is considered an acceptable method of aerating EtO sterilized items.
14. 250°F and 270°F are two established temperature settings for steam sterilizers.
15. EtO sterilizers are available that can perform both sterilizing and aeration.

MATCHING

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|---|------------------------------------|
| ___ 16. Recently developed sterilizer technology. | A. dental office or clinic |
| ___ 17. One of the most reliable methods for sterilizing heat and moisture sensitive items. | B. sterilizing |
| ___ 18. Component part of a steam sterilizer that turns steam into water vapor following a cycle. | C. plasma and chemical sterilizers |
| ___ 19. The microorganism and the cellular debris are literally burned up in the sterilizing process. | D. EtO sterilizer |
| ___ 20. Small gravity-displacement sterilizers can often be located. | E. dry heat sterilizer |
| ___ 21. The process that causes the destruction of all forms of microbial life, including the most resistant types of spore-forming bacteria. | F. condenser |